

REMARKS

I. Claim Rejections-35 USC § 112

Claims 9-21 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states:

- (a) Claim 9 is incomplete as it is dependent on non-elected Claim 1.

Applicants have amended claim 9 to make it not depend from claim 1, thus alleviating this rejection.

- (b) Claim 9 encompasses a method of improving weight gain, etc., in all animals, however, in line 3 the recitation of “an animal post-weaning,” indicates that the animal must be a mammal (as only mammals are weaned), thus the claim is indefinite.

Applicants have amended claim 9 by removing any recitation to “an animal post-weaning,” and substituting --at times of stress-- thus alleviating this rejection. Applicants respectfully request Examiner to withdraw this rejection.

- (c) Claim 11 is indefinite in the recitation of “chicken” as it is unclear just when a chicken would be considered “post-weaning” as chickens are not weaned.

Applicants amendment to claim 9 should place claim 11 in allowable form. Applicants respectfully request Examiner to withdraw this rejection.

- (d) Claim 13 is indefinite in the recitation of “underweight” as it is unclear just what pigs would, and would not, be encompassed by the term. Thus, the metes and bounds of the claim are not defined.

Applicants have amended claim 13 by reciting what pigs would be encompassed within this term, thus defining the metes and bounds of the claim.

III. Claim Rejections-35 USC § 103

Claims 9-18 and 21 were rejected under 35 USC § 103(a) as being unpatentable over US Patent No. 4,816,252 in view of Japan Patent No. 61-132143 (abstract) and US Patent No. 4,623,541.

The Examiner states the '252 patent teaches a method of comprising the administration of IgG supplements in the water source of an animal, including a cow, "post-weaning," for the transfer of passive immunity to said animals (see particularly col. 4, lines 64-67 and col. 24, lines 55-60). The Examiner further states the reference differs from the claimed invention in that it does not teach the specific use of animal plasma-derived globulins in specific concentrations, i.e., at least 15% IgG, in a dispersed concentration of about 0.375 to about 3.0% by weight, and a concentration of about 0.1-0.75% IgG by weight.

The Examiner states Japan Patent No. 61-132143 teaches the use of immunoglobulins as feed supplements to promote weight gain in pigs.

Additionally, the Examiner states the '541 patent teaches the use of animal plasma-derived immunoglobulins in a liquid feed source that provides for both immunological protection and increased weight gain in piglets (see Example 1 and Biological (Animal) Test) in concentrations encompassing the claimed limitations of "about 0.375 to about 3% globulin concentrate", "about 0.1-0.75% concentration of IgG", and "a dose of 0.5 immunoglobulin/hd/day or more", and including additives and nutrients. The Examiner states the reference further teaches the use of animal plasma (blood) for the convenient production of high purity immunoglobulins (see col. 3, lines 6-12).

The Examiner concludes it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to perform a method comprising administering

immunoglobulins in the water source of an animal, including a cow, "post-weaning" as taught by the '252 patent, or to a piglet to promote weight gain, as taught by Japan Patent No. 61-132143, it would have obvious to use a globulin concentrate as a feed supplement for piglets and to optimize the concentration of immunoglobulin for maximum weight gain and growth as well as decreased morbidity and mortality. One of ordinary skill in the art at the time the invention was made would have been motivated to encompass the claimed dosages and the claimed additives in order to achieve the referenced passive immunity and nourishment, as taught by the '541 patent, as the optimization of various concentrations and dosages would be required by animals of different ages and weights with different nutritional and immunological needs and would have been well within the purview of one of skill in the art at the time of the invention. Further, one of ordinary skill in the art at the time the invention was made would have been motivated to substitute immunoglobulins derived from animal plasma because animal plasma (blood) provides a convenient source for the production of high purity immunoglobulins, as taught by the '541 patent.

Applicants traverse this rejection. "Unexpected results tend to suggest that the invention would not have been obvious because they run contrary to the understanding and expectation in the art." See, e.g., United States v. Adams, 383 US 39, 51 (1966). Attached herewith is a 132 declaration from Eric M. Weaver establishing that growth performance in pigs and chicks was improved upon the addition of plasma protein to the drinking water well beyond the expected plasma protein response when included in dry feed. As summarized here, Applicants' declaration demonstrates that compared to the control pigs, the addition of a globulin concentrate (2.5%) to the drinking water improved daily gain (297%) and an increase in daily feed intake (133%), when the globulin concentrate from animal plasma was included in the drinking water of weaned

pigs as measured by the Applicants. (See Declaration, page 1, (3)). It is important to note that this response was observed in pigs consuming a diet supplemented with plasma proteins. (See Declaration, page 1, (3)). More importantly, this magnitude of response was well outside the expected response to plasma when included in the dry feed. (See Declaration, Table 1).

Similarly, in tests conducted with broiler chicks to evaluate the effect of adding plasma (defined in spec. on p. 10, lines 12-13 and p. 12, lines 23-26) to feed or water, Applicants surprisingly found that the daily gain improved when plasma was included in the water but not when it was included in the feed. (See Declaration p. 2, (6) and Table 2). Thus, these results demonstrated unexpected results in that the addition of plasma protein to the drinking water resulted in improvements in growth performance well beyond the expected plasma response.

Moreover, there is no teaching or suggestion in either of the references that they be combined in the manner suggested by the Examiner. Absent such a suggestion, a person skilled in the art who was looking to synthesize a water-stable, immunoglobulin concentrate based on animal plasma that improves the health and growth rate of animals at times of stress, especially post-weaning and had no prior knowledge of Applicants' claimed invention, would consult the particular combination of references suggested by the Examiner. None of the cited references suggest combining, nor provides any motivation to do so, the elements of taking a substantially pure, plasma-derived globulin that is water stable and placing it as a stock solution in the animal's water source and not in feed. "Rarely, however, will the skill in the art component operate to supply missing knowledge or prior art to reach an obviousness judgment." See W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F. 2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

In any event, the method that results from the Examiner's proposed combination of references would not meet the terms of Applicants proposed amendments to the rejected claims. As stated by the Examiner, the '252 patent fails to teach the specific use of animal plasma-derived globulins to promote weight gain and growth nor administration of the globulins in specific concentrations. Thus, such feature would be lacking in any combination. Moreover, the '252 patent encompasses a process for extracting immunoglobulins from milk. (See e.g., col. 4, lines 54-56 and col. 6, lines 15-18).

Similarly, the Japanese patent, teaches a blended feed comprising both a globulin-containing substance made from blood or milk and an antimicrobial agent. Moreover, this blend is placed in the common feed for the animal. The Japanese patent fails to teach a water-stable globulin concentrate, used in the animals water source.

Bear in mind that when such factors such as solution of a different problem and the like (all of which are cognizable as part of the "invention as a whole") are described in the specification, they must be taken into account in determining, in the first instance, whether the prior art presents a prima facie case of obviousness. In re Wright, 6 USPQ2d, 1959, 1962 (1988). Patent '541 fails to teach a globulin composition readily dissolvable in water that remains stable in a highly concentrated solution that does not obstruct water lines. US Patent '541 uses the immunoglobulins with skim milk powder. (See Example 1 col. 5, lines 55-65 and col. 6, lines 2-7). In fact, in the method employed by patent '541, the immunoglobins are blended with condensed skim milk. The Applicants directly speak to the potential problems that may occur as a result of the concentration of spray-dried animal plasma in a milk replacement product (see specification, page 9, lines 19-26), as contemplated by patent '541. If the concentration of spray-dried animal plasma in a milk replacement product is high enough and the

material is given enough time to form a protein matrix, this could result in plugging most water-delivery devices (see specification page 5, lines 4-8). This is a problem contemplated and avoided by the present invention. The water-dissolvable, stable, globulin concentrate of the present invention involves a raw globulin concentrate in liquid form. The concentrations of the IgG and the globulin concentrate are those in water. (See specification, page 16).

Unlike the combination proposed by the Examiner, the present invention deals with a purified water-stable immunoglobulin concentrate, wherein its composition is a plasma-based, substantially purified globulin concentrate, in which "substantially purified", defined on page 10 of the specification, refers to the fact that the globulin concentrate contains insufficient amounts of other substances that will cause the concentrate to clot or gel in water.

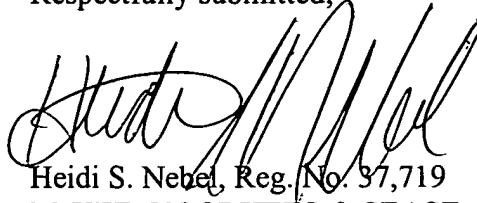
Therefore, claims 9-18 and 21 are patently distinct from Patent '252 in view of the Japanese patent, and Patent '541. Applicants respectfully request Examiner to withdraw this rejection.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Heidi S. Nebel", written over the printed name.

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**AMENDMENT — VERSION WITH MARKINGS
TO SHOW CHANGES MADE**

In the Specification

Please replace the paragraph at page 13, beginning at line 16 with the following:

In addition, one could simply inject the water-stable plasma into the water as the immunoglobulin source. Either serum or plasma may be used as an immunoglobulin [source] source in the globulin concentrate product. The further processing to concentrate immunoglobulin simply ensures fewer problems with line obstruction because less protein will be injected into the line.

In the Claims

Please amend the claims as follows:

9. (Amended)

A method of improving weight gain and growth, while decreasing morbidity and mortality in animals comprising:
administering a supplement to an animal [post-weaning] at times of stress through the animal's water source, said supplement comprising [the] a water-stable globulin concentrate [of claim 1].

13. (Amended)

A method according to claim 12 wherein the pig is underweight from a starvation period post-weaning.

15. (Amended)

A method according to claim 14 wherein the concentration of IgG in the water is from [about] approximately 0.1-0.75% by weight.

Please add the following new claims:

22. (New)

The method according to claim 9 wherein the globulin concentrate contains at least 15% by weight IgG.

23. (New)

A method of improving weight gain and growth, while decreasing morbidity and mortality in animals comprising:
administering a supplement to an animal at times of stress through the animal's water source,
said supplement comprising a water-stable globulin concentrate.

24. (New)

A method of improving weight gain and growth, while decreasing morbidity and mortality in animals comprising:
administering a supplement to an animal at times of stress through the animal's water source,
said supplement comprising a water miscible and stable globulin concentrate derived from animal plasma, the globulin concentrate containing at least 15% by weight IgG.